DEC 2 0 2001

510(k) Summary

Malleable Surgical Lightstic™ 180

K013901

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR §807 for the Malleable Surgical Lightstic™ 180.

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Joseph Curtis
10 Commerce Way
Norton, MA 02766
Telephone: (508) 285-1700
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Contact Person: same

Date Prepared: June 22, 2001

Name of Device and Name/Address of Sponsor

Surgical Lightstic™ 180
CardioFocus, Inc.
10 Commerce Way
Norton, MA 02766

Common or Usual Name

Laser Tissue Coagulator

Classification Name

Surgical Laser Instrument Accessories

Predicate Devices

The Malleable Surgical Lightstic 180 for use in cardiac tissue is identical to the current Surgical Lightstic 180 (K011988), and substantially equivalent for indications for use in cardiac tissue.

Intended Use

The Malleable Surgical Lightstic™ 180 is intended to be used as a surgical instrument for coagulation of soft tissue (including cardiac tissue) in conjunction with or without endoscopic equipment (including laparoscopes, hysteroscopes, bronchoscopes, cystoscopes, gastroscopes, colonoscopes), in the contact or non-contact mode in both open or closed surgical procedures (with or without handpiece). Its intended use is identical to the current Surgical Lightstic™ 180 (K011988)

Technological Characteristics and Substantial Equivalence

From a clinical perspective and comparing design specifications, the CardioFocus Malleable Surgical Lightstic™ 180 and the CardioFocus predicate device are substantially equivalent and have the same intended use.

CardioFocus, Inc. believes the minor differences of the CardioFocus Malleable Surgical Lightstic™ 180 and its predicate Surgical Lightstic™ 180 fiber laser accessories should not raise any concerns regarding the overall safety and effectiveness.

Performance Data

None required.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Joseph Curtis
Vice President of Clinical
and Regulatory Affairs
CardioFocus. Inc.
10 Commerce Way
Norton, Massachusetts 02766

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Re: K013901
Trade/Device Name: Malleable Surgical Lightstic™ 180
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: November 21, 2001
Received: November 26, 2001

Dear Mr. Curtis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K013901

Device Name: Malleable Surgical Lightstic™ 180

Indications For Use: Coagulation of Cardiac Tissue

Note: These are identical indications to the already cleared indications for market release in K011988.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013901

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR §801.109)